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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. 2:24-cv-00909 Hon. Stanley R. Chesler, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS** ***Document Electronically Filed***

Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs") as follows[1]:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") of Abbreviated New Drug Application ("ANDA") No. 219000 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product prior to the expiration of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent"). Collectively, the '712 patent, '476 patent, '509 patent, '510 patent, '156 patent, '808, patent, '512 patent, '447 patent, '888 patent, '889 patent, '637 patent, and '643 patent are referred to herein as the "Patents-in-Suit."

ANSWER: Cipla admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Cipla admits that Cipla Limited prepared and submitted Cipla's Abbreviated New Drug Application ("ANDA") No. 219000 ("Cipla's ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA ("Cipla's ANDA Product") prior to the expiration of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint. Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in the Complaint except those specifically admitted.

patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") (collectively, the "Patents-in-Suit"). Cipla denies the remaining allegations in paragraph 1.

PARTIES

Teva

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

Cipla

4. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

ANSWER: Cipla admits that Cipla Limited is a company organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Cipla admits that Cipla Limited manufactures pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 4.

5. On information and belief, Defendant Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd., and is controlled and dominated by Cipla Ltd. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

ANSWER: Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla admits that Cipla USA, Inc. distributes pharmaceutical drug products, including generic drug products, for sale. Cipla denies the remaining allegations in paragraph 5.

6. On information and belief, Cipla Ltd., acting in concert with Cipla USA, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Cipla Ltd., acting in concert with Cipla USA, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Cipla admits that Cipla Limited seeks regulatory approval of pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 6.

7. On information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's Beclomethasone Dipropionate Inhalation Aerosol, 40 mcg ("Cipla's ANDA Product") throughout the United States, including in New Jersey.

ANSWER: Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture use and/or sale of Cipla's ANDA Product. Cipla denies the remaining allegations in paragraph 7.

8. On information and belief, Cipla Ltd. and Cipla USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Cipla's ANDA Product at issue.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla denies any and all remaining allegations in paragraph 8.

9. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Ltd. and Cipla USA, Inc. will act in concert to market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 9 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

10. On information and belief, following any FDA approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 10 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

11. On information and belief, following any FDA approval of Cipla's ANDA, Cipla knows and intends that Cipla's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 11 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

ANSWER: In response to paragraph 12, Cipla repeats and realleges its responses to the allegations of paragraphs 1–11 of the Complaint as if fully set forth herein.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Cipla does not contest subject matter jurisdiction.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 14.

15. This Court has personal jurisdiction over Cipla USA, Inc. because, among other things, Cipla USA, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA, Inc. is a company with a principal place of business in New Jersey. On information and belief, Cipla USA, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 15.

16. On information and belief, Cipla USA, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Cipla Ltd.

ANSWER: Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations of paragraph 16.

17. On information and belief, Cipla USA, Inc., acting as the agent of Cipla Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Cipla Ltd. or for which Cipla is the named applicant on approved ANDAs.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic pharmaceutical drug products. Cipla admits that Cipla Limited manufactures and/or seeks regulatory approval of pharmaceutical drug products, including generic pharmaceutical drug products. Cipla denies the remaining allegations of paragraph 17.

18. This Court has personal jurisdiction over Cipla Ltd. because, among other things, Cipla Ltd. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla

Ltd. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic pharmaceuticals. Cipla denies the remaining allegations of paragraph 18.

19. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because, among other things, on information and belief: (1) Cipla USA, Inc. and Cipla Ltd. acted in concert to file Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) Cipla USA, Inc. and Cipla Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, upon approval of Cipla's ANDA, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j). Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the product described in Cipla's ANDA. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 19.

20. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because Cipla USA, Inc. and Cipla Ltd. regularly (1) engage in patent litigation concerning FDA approved branded drug products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc. & Norton (Waterford) Ltd. v. Cipla Ltd.*, Civil Action No. 20-14890 (JXN)(MAH) (D.N.J.); *Par Pharmaceutical, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-1150 (MCA)(JBC) (D.N.J.); *Fennec Pharmaceuticals, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-123 (JKS)(MAH) (D.N.J.); *Celgene Corp. v. Cipla Ltd.*, Civil Action No. 19-14731 (SDW)(LDW) (D.N.J.); *Cubist Pharm. LLC v. Cipla USA, Inc. & Cipla Ltd.*, Civil Action No. 19-12920 (BRM)(ZNQ) (D.N.J.).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 20.

21. For the above reasons, it would not be unfair or unreasonable for Cipla USA, Inc. and/or Cipla Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 21.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

ANSWER: In response to paragraph 22, Cipla repeats and realleges its responses to the allegations of paragraphs 1–21 of the Complaint as if fully set forth herein.

23. Venue is proper in this district for Cipla USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla USA, Inc. is a company with a principal place of business in New Jersey and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla denies the remaining allegations of paragraph 23.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Cipla Ltd., at least because, on information and belief, Cipla Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is a company organized and existing under the laws of India. Cipla denies the remaining allegations of paragraph 24.

BACKGROUND

25. Teva is the holder of New Drug Application ("NDA") No. 207921 for Qvar RediHaler® 40 mcg (beclomethasone dipropionate, 40 mcg) Inhalation Aerosol. Teva's Qvar RediHaler® inhaler is approved by FDA for maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age and older.

ANSWER: Cipla admits that New Drug Application ("NDA") No. 207921 is approved by FDA. Cipla admits that according to the prescribing information for QVAR REDIHALER™, QVAR REDIHALER is a corticosteroid indicated for: "[m]aintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older." Cipla states that FDA's electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange

Book") lists Norton Waterford Ltd. as the holder of NDA 207921. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 25 and therefore denies them.

The '712 Patent

26. The '712 patent, entitled "Metered-Dose Inhaler" (Exhibit A), duly and legally issued on March 13, 2012.

ANSWER: Cipla admits that Exhibit A to the Complaint purports to be a copy of the '712 patent. Cipla admits that the '712 patent is titled "Metered-Dose Inhaler" and lists March 13, 2012 as the issue date. Cipla denies the remaining allegations of paragraph 26.

27. Norton is the owner and assignee of the '712 patent.

ANSWER: According to the U.S. Patent and Trademark Office assignment database, Ivax Pharmaceuticals Ireland is listed as the assignee of the '712 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 27 and therefore denies them.

28. The '712 patent is listed in connection with the Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 28.

29. Claim 1 of the '712 patent claims:

A dose counter for a metered-dose inhaler, the counter comprising:

an actuator;

a rotary gear;

a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,

the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;

a pawl to prevent reverse rotation of the rotary gear; and

a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,
the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: Cipla admits that paragraph 29 purports to recite claim 1 of the '712 patent.

Cipla denies any remaining allegations of paragraph 29.

30. Claim 18 of the '712 patent claims:
The use of a dose counter for preventing miscounting in a metered dose inhaler, the dose counter comprising:
an actuator;
a rotary gear;
a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,
the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
a pawl to prevent reverse rotation of the rotary gear; and
a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,
the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: Cipla admits that paragraph 30 purports to recite claim 18 of the '712 patent.

Cipla denies any remaining allegations of paragraph 30.

31. Claim 19 of the '712 patent claims:

> The use of a dose counter for preventing undercounting in a metered dose inhaler, the dose counter comprising:
>
> an actuator;
>
> a rotary gear;
>
> a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,
>
> the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
>
> a pawl to prevent reverse rotation of the rotary gear; and
>
> a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
>
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,
>
> the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: Cipla admits that paragraph 31 purports to recite claim 19 of the '712 patent. Cipla denies any remaining allegations of paragraph 31.

The '476 Patent

32. The '476 patent, entitled "Inhaler" (Exhibit B), duly and legally issued on January 13, 2015.

ANSWER: Cipla admits that Exhibit B to the Complaint purports to be a copy of the '476 patent. Cipla admits that the '476 patent is titled "Inhaler" and lists January 13, 2015 as the date of patent. Cipla denies any remaining allegations of paragraph 32.

33. Norton is the owner and assignee of the '476 patent.

ANSWER: According to the U.S. Patent and Trademark Office assignment database, Ivax Pharmaceuticals Ireland is listed as the assignee of the '476 patent. Cipla lacks sufficient

information or knowledge to admit or deny the remaining allegations in paragraph 33 and therefore denies them.

34. The '476 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 34.

35. Claim 1 of the '476 patent claims:

An inhaler for delivering medicament to a patient, the inhaler comprising

a housing for holding the medicament and having an air inlet means and a medicament delivery port which together define an air flow path into which the medicament is dispensed,

wherein the air inlet means comprises an array of elongate apertures formed in the housing,

wherein long sides of adjacent apertures face each other, and each aperture being provided with a respective different opening in an outer surface of the housing, and

wherein the opening of each aperture extends in two different planes such that, if at least a part of the opening is covered in one of two different planes during inhalation by the patient, a void space is created between a cover and the aperture so as to provide an air flow path through the void space to the at least one aperture,

wherein a raised formation is provided in the outer surface of the housing between adjacent apertures to either limit or prevent a covered opening.

ANSWER: Cipla admits that paragraph 35 purports to recite claim 1 of the '476 patent. Cipla denies any remaining allegations of paragraph 35.

36. Claim 17 of the '476 patent claims:

A metered-dose inhaler for delivering medicament to a patient, the inhaler comprising

a housing for holding the medicament and having an air inlet means and a medicament delivery port which together define an air flow path into which the medicament is dispensed,

wherein the housing comprises an elongate body and the air inlet means is provided in an end face of the elongate body,

> wherein the air inlet means comprises an array of elongate apertures formed in the housing, long sides of adjacent apertures facing each other, and each aperture being
> provided with a respective different opening in an outer surface of the housing,
> wherein each aperture is provided in a respective different recess in the outer surface of the housing, which recess defines the opening of the aperture,
> and wherein the opening of each aperture in the outer surface of the housing extends in two different planes defining an angle of at least 45 degrees to each other, such that, if at least a part of the opening is covered in one of the two different planes during inhalation by the patient, a void space is created between the patient and the aperture so as to provide an air flow path through the void space to the at least one aperture.

ANSWER: Cipla admits that paragraph 36 purports to recite claim 17 of the '476 patent. Cipla denies any remaining allegations of paragraph 36.

The '509 Patent

37. The '509 patent, entitled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement" (Exhibit C), duly and legally issued on July 17, 2018.

ANSWER: Cipla admits that Exhibit C to the Complaint purports to be a copy of the '509 patent. Cipla admits that the '509 patent is titled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement" and lists July 17, 2018 as the issue date. Cipla denies any remaining allegations in paragraph 37.

38. Norton is the owner and assignee of the '509 patent.

ANSWER: According to the '509 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '509 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 38 and therefore denies them.

39. The '509 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 39.

40. Claim 1 of the '509 Patent claims:

> A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge, wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

ANSWER: Cipla admits that paragraph 40 purports to recite claim 1 of the '509 patent. Cipla denies any remaining allegations of paragraph 40.

The '510 Patent

41. The '510 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit D), duly and legally issued on July 17, 2018.

ANSWER: Cipla admits that Exhibit D to the Complaint purports to be a copy of the '510 patent. Cipla admits that the '510 patent is titled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" and lists July 17, 2018 as the issue date. Cipla denies any remaining allegations of paragraph 41.

42. Norton is the owner and assignee of the '510 patent.

ANSWER: According to the '510 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '510 patent.

Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 42 and therefore denies them.

43. The ’510 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA’s Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 43.

44. Claim 1 of the ’510 patent claims:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing Indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and
> >
> > wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

ANSWER: Cipla admits that paragraph 44 purports to recite claim 1 of the ’510 patent. Cipla denies any remaining allegations of paragraph 44.

45. Claim 10 of the ’510 patent claims:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape
> >
> > structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a

first end of the main elongate tape structure and the tape positioning indicia,
wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

ANSWER: Cipla admits that paragraph 45 purports to recite claim 10 of the '510 patent. Cipla denies any remaining allegations of paragraph 45.

46. Claim 20 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,
wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

ANSWER: Cipla admits that paragraph 46 purports to recite claim 20 of the '510 patent. Cipla denies any remaining allegations of paragraph 46.

The '156 Patent

47. The '156 patent, entitled "Dose Counter for Inhaler and Method of Counting Doses" (Exhibit E), duly and legally issued on October 2, 2018.

ANSWER: Cipla admits that Exhibit E to the Complaint purports to be a copy of the '156 patent. Cipla admits that the '156 patent is titled "Dose Counter for Inhaler and Method for

Counting Doses" and lists October 2, 2018 as the issue date. Cipla denies any remaining allegations of paragraph 47.

48. Norton is the owner and assignee of the '156 patent.

ANSWER: According to the '156 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '156 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 48 and therefore denies them.

49. The '156 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 49.

50. Claim 1 of the '156 patent claims:

> A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
>
> > a ratchet wheel having a plurality of circumferentially spaced teeth,
> > an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
> > a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
> > a dosage indicator associated with the count pawl,
> > wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
> > wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps

> over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count, wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

ANSWER: Cipla admits that paragraph 50 purports to recite claim 1 of the '156 patent. Cipla denies any remaining allegations of paragraph 50.

The '808 Patent

51. The '808 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit F), duly and legally issued on February 18, 2020.

ANSWER: Cipla admits that Exhibit F to the Complaint purports to be a copy of the '808 patent. Cipla admits that the '808 patent is titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" and lists February 18, 2020 as the issue date. Cipla denies any remaining allegations of paragraph 51.

52. Norton is the owner and assignee of the '808 patent.

ANSWER: According to the '808 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '808 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 52 and therefore denies them.

53. The '808 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 53.

54. Claim 1 of the '808 patent claims:

> A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is

provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

ANSWER: Cipla admits that paragraph 54 purports to recite claim 1 of the '808 patent. Cipla denies any remaining allegations of paragraph 54.

The '512 Patent

55. The '512 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit G), duly and legally issued on June 30, 2020.

ANSWER: Cipla admits that Exhibit G to the Complaint purports to be a copy of the '512 patent. Cipla admits that the '512 patent is titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" and lists June 30, 2020 as the issue date. Cipla denies any remaining allegations of paragraph 55.

56. Norton is the owner and assignee of the '512 patent.

ANSWER: According to the '512 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '512 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 56 and therefore denies them.

57. The '512 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 57.

58. Claim 1 of the '512 patent claims:

An inhaler for inhaling medicament, the inhaler having:

A body for retaining a medicament canister; and

a dose counter, the dose counter having a moveable actuator and a chassis mounted on the body;

wherein one of the body and the chassis includes a plurality of apertures for receiving one or more pins on the other of

the body and the chassis,
wherein either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body, and
wherein the chassis comprises at least one of a pin or aperture heat staked to a respective aperture or pin of the body to mount the chassis to the body.

ANSWER: Cipla admits that paragraph 58 purports to recite claim 1 of the '512 patent. Cipla denies any remaining allegations of paragraph 58.

The '447 Patent

59. The '447 patent, entitled "Breath Actuated Inhaler" (Exhibit H), duly and legally issued on October 6, 2020.

ANSWER: Cipla admits that Exhibit H to the Complaint purports to be a copy of the '447 patent. Cipla admits that the '447 patent is titled "Breath Actuated Inhaler" and lists October 6, 2020 as the issue date. Cipla denies any remaining allegations of paragraph 59.

60. Norton is the owner and assignee of the '447 patent.

ANSWER: Cipla admits that Norton (Waterford) Limited is listed as the assignee of the '447 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 60 and therefore denies them.

61. The '447 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 61.

62. Claim 1 of the '447 patent claims:
A breath actuated metered dose inhaler comprising:
a canister fire system configured to provide a canister actuation force to fire a medicament containing canister in response to patient

inhalation, the canister fire system comprising a pneumatic force holding unit and having:
a rest configuration in which a metering valve of the canister is in a refill configuration;
a prepared configuration in which a canister actuation force is retained by a difference in pressure between an enclosed volume within the pneumatic force holding unit and atmospheric pressure, and in which prepared configuration the canister fire system is actuatable by patient inhalation induced airflow;
and a fire configuration in which the metering valve is in a dose delivery position;
wherein, in the prepared configuration, the force retained by the pneumatic force holding unit reduces but by less than about 6% over a period of 5 minutes.

ANSWER: Cipla admits that paragraph 62 purports to recite claim 1 of the ’447 patent.

Cipla denies any remaining allegations of paragraph 62.

63. Claim 10 of the ’447 patent claims:

A breath actuated metered dose inhaler comprising:

a canister fire system configured to provide a canister actuation force to fire a medicament containing canister in response to patient inhalation, the canister fire system comprising a pneumatic force holding unit and having:
a rest configuration in which a metering valve of the canister is in a refill configuration;
a prepared configuration in which a canister actuation force is retained by a difference in pressure between an enclosed volume within the pneumatic force holding unit and atmospheric pressure, and in which prepared configuration the canister fire system is actuatable by patient inhalation induced airflow;
and a fire configuration in which the metering valve is in a dose delivery position;
wherein, in the prepared configuration, the force retained by the pneumatic force holding unit reduces but by less than about 6% over a period of 5 minutes and wherein the pneumatic force holding unit further comprises a valve port comprising a relatively rigid valve seal surface configured to be sealably engaged by an elastomeric valve seal, wherein the relatively rigid valve seal surface has a surface roughness average (RA) of less than about 0.15 μm.

ANSWER: Cipla admits that paragraph 63 purports to recite claim 10 of the '447 patent. Cipla denies any remaining allegations of paragraph 63.

The '888 Patent

64. The '888 patent, entitled "Inhalers and Related Methods" (Exhibit I), duly and legally issued on July 26, 2022.

ANSWER: Cipla admits that Exhibit I to the Complaint purports to be a copy of the '888 patent. Cipla admits that the '888 patent is titled "Inhalers and Related Methods" and lists July 26, 2022 as the issue date. Cipla denies any remaining allegations of paragraph 64.

65. Norton is the owner and assignee of the '888 patent.

ANSWER: Cipla admits that Norton (Waterford) Limited is listed as the assignee of the '888 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 65 and therefore denies them.

66. The '888 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 66.

67. Claim 1 of the '888 patent claims:

A breath actuated inhaler having

a drive adapted to drive a pressurized canister so as to retract a metering valve stem into the pressurized canister to fire the pressurized canister,

the pressurized canister comprising a metering chamber and an interior reservoir, and being adapted to move during operation between 1 and 4 mm between end positions of its length of travel relative to the valve stem,

the drive being arranged to apply a firing force of greater than 35 N and less than 60 N to the pressurized canister at a position of the pressurized canister relative to the valve stem at which the pressurized canister fires,

the breath actuated inhaler further having a metering valve spring and a dose counter with a dose counter biasing element that cooperate together with the drive to hold the pressurized canister in a ready-to-fire configuration in which the pressurized canister is displaced from the end positions and the metering chamber is isolated from the atmosphere and wherefrom, in response to air flow, the pressurized canister is movable to close communication between the metering chamber and the interior reservoir and to open communication between the metering chamber and the atmosphere, and

a vacuum chamber external to the metering chamber, wherein the metering valve spring and the dose counter biasing element combine with a vacuum force from the vacuum chamber to oppose a force from the drive when the pressurized canister is in the ready-to-fire configuration.

ANSWER: Cipla admits that paragraph 67 purports to recite claim 1 of the '888 patent.

Cipla denies any remaining allegations of paragraph 67.

68. Claim 25 of the '888 patent claims:

A breath actuated inhaler having

a drive adapted to drive a pressurized canister so as to retract a metering valve stem into the pressurized canister to fire the pressurized canister,

the pressurized canister comprising a metering chamber and an interior reservoir, and being adapted to move during operation between 1 and 4 mm between end positions of its length of travel relative to the valve stem,

the drive being arranged to apply a firing force of greater than 35 N and less than 60 N to the pressurized canister at a position of the pressurized canister relative to the valve stem

at which the pressurized canister fires,

the breath actuated inhaler further having a metering valve spring and a dose counter with a dose counter biasing element that cooperate together with the drive to hold the pressurized canister in a ready-to-fire configuration in which the pressurized canister is displaced from the end positions and the metering chamber is isolated from the atmosphere and wherefrom, in response to air flow, the pressurized canister is movable to close communication between the metering chamber and the interior reservoir and to open communication between the metering chamber and the atmosphere,

the breath actuated inhaler further having an actuator system for operating the drive, wherein the actuator system includes a vacuum

> chamber external to the metering chamber having a vacuum release system operable to permit the drive to drive movement of the pressurized canister relative to the valve stem, and the metering valve spring, a vacuum force from the vacuum chamber, and the dose counter biasing element combine to oppose a force from the drive when the pressurized canister is in the ready-to-fire configuration.

ANSWER: Cipla admits that paragraph 68 purports to recite claim 25 of the '888 patent. Cipla denies any remaining allegations of paragraph 68.

The '889 Patent

69. The '889 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit J), duly and legally issued on July 26, 2022.

ANSWER: Cipla admits that Exhibit J to the Complaint purports to be a copy of the '889 patent. Cipla admits that the '889 patent is titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" and lists July 26, 2022 as the issue date. Cipla denies any remaining allegations of paragraph 69.

70. Norton is the owner and assignee of the '889 patent.

ANSWER: According to the '889 patent, Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are listed as assignees of the '889 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 70 and therefore denies them.

71. The '889 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 71.

72. Claim 1 of the '889 patent claims:

> An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto,

> the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

ANSWER: Cipla admits that paragraph 72 purports to recite claim 1 of the '889 patent. Cipla denies any remaining allegations of paragraph 72.

The '637 Patent

73. The '637 patent, entitled "Inhalers and Related Methods" (Exhibit K), duly and legally issued on January 24, 2023.

ANSWER: Cipla admits that Exhibit K to the Complaint purports to be a copy of the '637 patent. Cipla admits that the '637 patent is titled "Inhalers and Related Methods" and lists January 24, 2023 as the issue date. Cipla denies any remaining allegations of paragraph 73.

74. Norton is the owner and assignee of the '637 patent.

ANSWER: Cipla admits that Norton (Waterford) Limited is listed as the assignee of the '637 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 74 and therefore denies them.

75. The '637 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 75.

76. Claim 1 of the '637 patent claims:

A breath actuated inhaler comprising:

a main body for accommodating a medicament reservoir,

a canister fire system including
a trigger; and
a biasing element for moving a canister to release a dose in response to air flow,
a cap housing,
an interior chamber defined by the main body and the cap housing, the canister fire system and canister being enclosed within the interior chamber, and
a lock system including helical threads having non- overlapping and distinct thread segments for providing rotational attachment of the cap housing to the main body and a first lock member that cooperates with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,
wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping with respect to each other along the central axis, and
wherein the first lock member is interposed between the thread segments.

ANSWER: Cipla admits that paragraph 76 purports to recite claim 1 of the '637 patent.

Cipla denies any remaining allegations of paragraph 76.

77. Claim 28 of the '637 patent claims:
A breath actuated inhaler comprising
a main body for accommodating a medicament reservoir,
a canister fire system for moving a canister to release a dose in response to air flow,
a cap housing for enclosing the canister fire system and canister within an interior chamber defined by the main body and the cap housing, and in which the main body and the cap housing are formed of plastics material characterized in that a lock system is provided for locking the cap housing on the main body,
wherein the lock system includes:
helical threads having non-overlapping and distinct thread segments for providing rotational attachment of the cap housing on the main body; and
a first lock member that cooperates with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,
wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping

with respect to each other along the central axis, wherein the first lock member is interposed between the thread segments, and wherein a release torque required to overcome the lock system is more than 1 Nm and lower than 4 Nm.

ANSWER: Cipla admits that paragraph 77 purports to recite claim 28 of the '637 patent. Cipla denies any remaining allegations of paragraph 77.

The '643 Patent

78. The '643 patent, entitled "Inhalers and Related Methods" (Exhibit L), duly and legally issued on February 21, 2023.

ANSWER: Cipla denies that a copy of the '643 patent is attached as an Exhibit to the Complaint. Cipla admits that the '643 patent is titled "Inhalers and Related Methods" and lists February 21, 2023 as the issue date. Cipla denies any remaining allegations of paragraph 78.

79. Norton is the owner and assignee of the '643 patent.

ANSWER: Cipla admits that Norton (Waterford) Limited is listed as the assignee of the '643 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 79 and therefore denies them.

80. The '643 patent is listed in connection with Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that FDA's Orange Book associates the Patents-in-Suit with NDA 207921. Cipla denies any remaining allegations of paragraph 80.

81. Claim 1 of the '643 patent claims:

A method of metering inhalable substances, the method comprising:

providing a medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening

configured to permit flow between a transfer space inside the valve stem and the interior reservoir;
operating the medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber;
following the time period, orienting the interior reservoir above the metering chamber to permit the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and
administering, from the liquid replacement, 75% to 125% of labelled claim for a dose.

ANSWER: Cipla admits that paragraph 81 purports to recite claim 1 of the '643 patent.

Cipla denies any remaining allegations of paragraph 81.

82. Claim 35 of the '643 patent claims:

A method of metering an inhalable composition comprising:

discharging a first metered dose from a medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, configured to permit flow between the valve stem and the interior reservoir;
upon discharge of the first metered dose, causing the valve stem to be in a retracted position for a time period of about 2 minutes to about 24 hours during which the metering chamber stays open and exposed to atmosphere to permit atmospheric air to enter the metering chamber;
at an end of the time period, orienting the interior reservoir above the metering chamber to replace the atmospheric air within the metering chamber with a replacement liquid; and
actuating the medicament inhaler to discharge a second metered dose having 75% to 125% of labelled claim for a dose from the replacement liquid.

ANSWER: Cipla admits that paragraph 82 purports to recite claim 35 of the '643 patent.

Cipla denies any remaining allegations of paragraph 82.

83. Claim 36 of the '643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,

wherein the respiratory disease includes one or more of asthma and COPD, and the one or more active ingredients include one or more of corticosteroid, beclomethasone dipropionate, and tiotropium bromide.

ANSWER: Cipla admits that paragraph 83 purports to recite claim 36 of the ’643 patent.

Cipla denies any remaining allegations of paragraph 83.

84. Claim 37 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber

and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose, wherein the respiratory disease includes asthma, and the one or more active ingredients include corticosteroid.

ANSWER: Cipla admits that paragraph 84 purports to recite claim 37 of the '643 patent.

Cipla denies any remaining allegations of paragraph 84.

85. Claim 38 of the '643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-

actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;
following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;
while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and
administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,
wherein the respiratory disease includes asthma and the one or more active ingredients include beclomethasone dipropionate or tiotropium bromide.

ANSWER: Cipla admits that paragraph 85 purports to recite claim 38 of the '643 patent.

Cipla denies any remaining allegations of paragraph 85.

86. Claim 39 of the '643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;
operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;
following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;
while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air

within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and
administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,
wherein the respiratory disease includes COPD and the one or more active ingredients include corticosteroid.

ANSWER: Cipla admits that paragraph 86 purports to recite claim 39 of the '643 patent.

Cipla denies any remaining allegations of paragraph 86.

87. Claim 40 of the '643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;
operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;
following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;
while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,
wherein the respiratory disease includes COPD and the one or more active ingredients include beclomethasone dipropionate or tiotropium bromide.

ANSWER: Cipla admits that paragraph 87 purports to recite claim 40 of the '643 patent. Cipla denies any remaining allegations of paragraph 87.

ALLEGED INFRINGEMENT BY CIPLA

88. By letter dated January 4, 2024 ("Cipla's Notice Letter"), Cipla notified Teva that it had filed Paragraph IV Certifications with respect to the Patents-in-Suit and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit. On information and belief, Cipla's ANDA contains Paragraph IV Certifications asserting that Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the Patents-in-Suit are invalid.

ANSWER: Cipla admits by a letter dated January 4, 2024 ("Cipla's Notice Letter"), Cipla notified Plaintiffs that it was seeking approval from FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of Cipla's ANDA product before the expiration of the Patents-in-Suit. Cipla further admits that Cipla's Notice Letter notified Plaintiffs that Cipla's ANDA includes a paragraph IV certification that the Patents-in-Suit are alleged to be invalid, unenforceable, and/or not infringed. Cipla denies the remaining allegations of paragraph 88.

89. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Cipla admits that it submitted an ANDA seeking approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit. Cipla denies the remaining allegations of paragraph 89.

90. In Cipla's Notice Letter, Cipla stated that the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

ANSWER: Cipla admits that Cipla's Notice Letter stated that the "established name of the proposed drug product that is the subject of Cipla's ANDA is Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg." Cipla denies the remaining allegations of paragraph 90.

91. In Cipla's Notice Letter, Cipla stated that the active ingredient of Cipla's ANDA Product is beclomethasone dipropionate.

ANSWER: Cipla admits that Cipla's Notice Letter stated that the "active ingredient of Cipla's proposed drug product is beclomethasone dipropionate." Cipla denies the remaining allegations of paragraph 91.

92. In Cipla's Notice Letter, Cipla stated that the proposed dosage strength of Cipla's ANDA Product is 40 mcg per actuation.

ANSWER: Cipla admits that Cipla's Notice Letter stated, "[t]he dosage form of the proposed drug product is 40 mcg per actuation." Cipla denies the remaining allegations of paragraph 92.

93. In Cipla's Notice Letter, Cipla stated that the established name of the proposed drug product that is the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

ANSWER: Cipla admits that Cipla's Notice Letter stated that the "established name of the proposed drug product that is the subject of Cipla's ANDA is Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg." Cipla denies the remaining allegations of paragraph 93.

94. Cipla's Notice Letter purported to provide Teva with an Offer of Confidential Access ("OCA") to portions of Cipla's ANDA. That offer, however, was subject to various unreasonably restrictive conditions.

ANSWER: Cipla admits that it provided an offer of confidential access to Cipla's ANDA with its Notice Letter ("OCA"). Cipla denies the remaining allegations of paragraph 94.

95. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Offer of Confidential Access. The parties did not agree on terms

under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, and Cipla refused to produce samples of Cipla's ANDA Product and other internal documents and material relevant to infringement.

ANSWER: Cipla admits that counsel for Plaintiffs and Cipla communicated regarding Cipla's OCA. Cipla denies the remaining allegations of paragraph 95.

96. On January 16, 2024, Teva's counsel sent Cipla's counsel a letter requesting documents and identifying various unreasonably restrictive terms in Cipla's OCA, including but not limited to restrictions on the conduct of Teva's outside counsel in future post-grant and FDA proceedings, prohibitions on providing information to outside consultants, choice of law, and limitations on the scope of documents Cipla would provide to Teva.

ANSWER: Cipla admits that Teva's counsel sent Cipla's counsel a letter on January 16, 2024. Cipla denies the remaining allegations of paragraph 96.

97. On January 25, 2024, Cipla's counsel sent Teva's counsel an email refusing to provide the documents and materials requested by Teva and necessary to evaluate Cipla's ANDA Products for infringement.

ANSWER: Cipla admits that counsel for Cipla sent Teva's counsel an email on January 25, 2024. Cipla denies the remaining allegations of paragraph 97.

98. On February 8, 2024, Teva's counsel reiterated to Cipla's counsel via email Teva's need for specific materials to evaluate infringement and proposed reasonable terms for confidentiality protections.

ANSWER: Cipla admits that counsel for Teva sent Cipla's counsel an email on February 8, 2024. Cipla denies the remaining allegations of paragraph 98.

99. Teva's counsel has not received a response to its February 8, 2024 email.

ANSWER: Cipla admits that the complaint was filed before Cipla's counsel had an opportunity to respond to the February 8, 2024 email from Teva's counsel.

100. Cipla's Notice Letter appends a document titled "Detailed Statement" asserting that the commercial manufacture, use, or sale of Cipla's ANDA Product will not infringe any of the Patents-in-Suit. However, Cipla's Notice Letter and "Detailed Statement" do not provide information regarding Cipla's ANDA Product sufficient to evaluate Cipla's assertions of

noninfringement. Indeed, Cipla's Notice Letter and "Detailed Statement" fail to provide any information regarding Cipla's ANDA Product beyond the unsupported and unexplained assertions by Cipla's attorneys that Cipla's ANDA Product do not meet certain limitations of each of the Patents-in-Suit.

ANSWER: Cipla admits that its Notice Letter included a "Detailed Factual and Legal Basis for Cipla's Paragraph IV Certification" that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed. Cipla denies the remaining allegations of paragraph 100.

101. This action is being commenced before the expiration of forty-five days from the date of the receipt of Cipla's Notice Letter.

ANSWER: Admitted.

COUNT 1 – ALLEGED INFRINGEMENT BY CIPLA OF THE '712 PATENT UNDER 35 U.S.C. § 271(e)(2)

102. Plaintiffs incorporate each of the preceding paragraphs 1–97 as if fully set forth herein.

ANSWER: In response to paragraph 102, Cipla repeats and realleges its responses to the allegations of paragraphs 1–101 of the Complaint as if fully set forth herein.

103. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '712 patent was an act of infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

104. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

105. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

106. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above.

ANSWER: Denied.

107. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '712 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

108. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '712 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '712 patent after approval of Cipla's ANDA.

ANSWER: Denied.

109. The foregoing actions by Cipla constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Denied.

110. On information and belief, Cipla has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Denied.

111. Unless Cipla is enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 111.

COUNT 2 – ALLEGED INFRINGEMENT BY CIPLA

OF THE '476 PATENT UNDER 35 U.S.C. § 271(e)(2)

112. Plaintiffs incorporate each of the preceding paragraphs 1–107 as if fully set forth herein.

ANSWER: In response to paragraph 112, Cipla repeats and realleges its responses to the allegations of paragraphs 1–111 of the Complaint as if fully set forth herein.

113. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '476 patent was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

114. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 17 of the '476 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

115. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

116. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 17 of the '476 patent, recited above.

ANSWER: Denied.

117. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '476 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

118. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '476 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing

use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '476 patent after approval of Cipla's ANDA.

ANSWER: Denied.

119. The foregoing actions by Cipla constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and contribution to the infringement by others of the '476 patent.

ANSWER: Denied.

120. On information and belief, Cipla has acted with full knowledge of the '476 patent and without a reasonable basis for believing that it would not be liable for infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent.

ANSWER: Denied.

121. Unless Cipla is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 121 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 121.

COUNT 3 – ALLEGED INFRINGEMENT BY CIPLA OF THE '509 PATENT UNDER 35 U.S.C. § 271(e)(2)

122. Plaintiffs incorporate each of the preceding paragraphs 1–117 as if fully set forth herein.

ANSWER: In response to paragraph 122, Cipla repeats and realleges its responses to the allegations of paragraphs 1–121 of the Complaint as if fully set forth herein.

123. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '509 patent was an act of infringement of the '509 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

124. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

125. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

126. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '509 patent, recited above.

ANSWER: Denied.

127. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '509 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

128. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '509 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '509 patent after approval of Cipla's ANDA.

ANSWER: Denied.

129. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

ANSWER: Denied.

130. On information and belief, Cipla has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

ANSWER: Denied.

131. Unless Cipla is enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 131 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 131.

COUNT 4 – ALLEGED INFRINGEMENT BY CIPLA OF THE '510 PATENT UNDER 35 U.S.C. § 271(e)(2)

132. Plaintiffs incorporate each of the preceding paragraphs 1–127 as if fully set forth herein.

ANSWER: In response to paragraph 132, Cipla repeats and realleges its responses to the allegations of paragraphs 1–131 of the Complaint as if fully set forth herein.

133. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '510 patent was an act of infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

134. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

135. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

136. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

ANSWER: Denied.

137. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '510 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

138. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '510 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '510 patent after approval of Cipla's ANDA.

ANSWER: Denied.

139. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

ANSWER: Denied.

140. On information and belief, Cipla has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

ANSWER: Denied.

141. Unless Cipla is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 141 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 141.

COUNT 5 – ALLEGED INFRINGEMENT BY CIPLA OF THE '156 PATENT UNDER 35 U.S.C. § 271(e)(2)

142. Plaintiffs incorporate each of the preceding paragraphs 1–137 as if fully set forth herein.

ANSWER: In response to paragraph 142, Cipla repeats and realleges its responses to the allegations of paragraphs 1–141 of the Complaint as if fully set forth herein.

143. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '156 patent was an act of infringement of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

144. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

145. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

146. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '156 patent, recited above.

ANSWER: Denied.

147. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

148. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '156 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '156 patent after approval of Cipla's ANDA.

ANSWER: Denied.

149. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

ANSWER: Denied.

150. On information and belief, Cipla has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

ANSWER: Denied.

151. Unless Cipla is enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 151 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 151.

COUNT 6 – ALLEGED INFRINGEMENT BY CIPLA OF THE '808 PATENT UNDER 35 U.S.C. § 271(e)(2)

152. Plaintiffs incorporate each of the preceding paragraphs 1–147 as if fully set forth herein.

ANSWER: In response to paragraph 152, Cipla repeats and realleges its responses to the allegations of paragraphs 1–152 of the Complaint as if fully set forth herein.

153. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '808 patent was an act of infringement of the '808 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

154. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

155. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

156. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '808 patent, recited above.

ANSWER: Denied.

157. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

158. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '808 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '808 patent after approval of Cipla's ANDA.

ANSWER: Denied.

159. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Denied.

160. On information and belief, Cipla has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Denied.

161. Unless Cipla is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 161 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 161.

COUNT 7 – ALLEGED INFRINGEMENT BY CIPLA OF THE '512 PATENT UNDER 35 U.S.C. § 271(e)(2)

162. Plaintiffs incorporate each of the preceding paragraphs 1–157 as if fully set forth herein.

ANSWER: In response to paragraph 162, Cipla repeats and realleges its responses to the allegations of paragraphs 1–161 of the Complaint as if fully set forth herein.

163. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '512 patent was an act of infringement of the '512 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

164. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

165. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

166. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '512 patent, recited above.

ANSWER: Denied.

167. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '512 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

168. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '512 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '512 patent after approval of Cipla's ANDA.

ANSWER: Denied.

169. The foregoing actions by Cipla constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

ANSWER: Denied.

170. On information and belief, Cipla has acted with full knowledge of the '512 patent and without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

ANSWER: Denied.

171. Unless Cipla is enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 171 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 171.

COUNT 8 – ALLEGED INFRINGEMENT BY CIPLA OF THE '447 PATENT UNDER 35 U.S.C. § 271(e)(2)

172. Plaintiffs incorporate each of the preceding paragraphs 1–167 as if fully set forth herein.

ANSWER: In response to paragraph 172, Cipla repeats and realleges its responses to the allegations of paragraphs 1–171 of the Complaint as if fully set forth herein.

173. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '447 patent was an act of infringement of the '447 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

174. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 10 of the '447 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

175. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

176. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 10 of the '447 patent, recited above.

ANSWER: Denied.

177. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '447 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

178. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '447 patent after approval of Cipla's ANDA.

ANSWER: Denied.

179. The foregoing actions by Cipla constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and contribution to the infringement by others of the '447 patent.

ANSWER: Denied.

180. On information and belief, Cipla has acted with full knowledge of the '447 patent and without a reasonable basis for believing that it would not be liable for infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent.

ANSWER: Denied.

181. Unless Cipla is enjoined from infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 181 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 181.

COUNT 9 – ALLEGED INFRINGEMENT BY CIPLA OF THE '888 PATENT UNDER 35 U.S.C. § 271(e)(2)

182. Plaintiffs incorporate each of the preceding paragraphs 1–177 as if fully set forth herein.

ANSWER: In response to paragraph 182, Cipla repeats and realleges its responses to the allegations of paragraphs 1–181 of the Complaint as if fully set forth herein.

183. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '888 patent was an act of infringement of the '888 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

184. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 25 of the '888 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

185. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

186. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 25 of the '888 patent, recited above.

ANSWER: Denied.

187. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '888 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

188. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '888 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '888 patent after approval of Cipla's ANDA.

ANSWER: Denied.

189. The foregoing actions by Cipla constitute and/or will constitute infringement of the '888 patent, active inducement of infringement of the '888 patent, and contribution to the infringement by others of the '888 patent.

ANSWER: Denied.

190. On information and belief, Cipla has acted with full knowledge of the '888 patent and without a reasonable basis for believing that it would not be liable for infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent.

ANSWER: Denied.

191. Unless Cipla is enjoined from infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 191 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 191.

COUNT 10 – ALLEGED INFRINGEMENT BY CIPLA OF THE '889 PATENT UNDER 35 U.S.C. § 271(e)(2)

192. Plaintiffs incorporate each of the preceding paragraphs 1–187 as if fully set forth herein.

ANSWER: In response to paragraph 192, Cipla repeats and realleges its responses to the allegations of paragraphs 1–191 of the Complaint as if fully set forth herein.

193. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '889 patent was an act of infringement of the '889 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

194. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '889 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

195. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

196. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '889 patent, recited above.

ANSWER: Denied.

197. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '889 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

198. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '889 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '889 patent after approval of Cipla's ANDA.

ANSWER: Denied.

199. The foregoing actions by Cipla constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Denied.

200. On information and belief, Cipla has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Denied.

201. Unless Cipla is enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 201 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 201.

COUNT 11 – ALLEGED INFRINGEMENT BY CIPLA OF THE '637 PATENT UNDER 35 U.S.C. § 271(e)(2)

202. Plaintiffs incorporate each of the preceding paragraphs 1–197 as if fully set forth herein.

ANSWER: In response to paragraph 202, Cipla repeats and realleges its responses to the allegations of paragraphs 1–201 of the Complaint as if fully set forth herein.

203. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '637 patent was an act of infringement of the '637 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

204. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 28 of the '637 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

205. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

206. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 28 of the '637 patent, recited above.

ANSWER: Denied.

207. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '637 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

208. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '637 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '637 patent after approval of Cipla's ANDA.

ANSWER: Denied.

209. The foregoing actions by Cipla constitute and/or will constitute infringement of the '637 patent, active inducement of infringement of the '637 patent, and contribution to the infringement by others of the '637 patent.

ANSWER: Denied.

210. On information and belief, Cipla has acted with full knowledge of the '637 patent and without a reasonable basis for believing that it would not be liable for infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent.

ANSWER: Denied.

211. Unless Cipla is enjoined from infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 211 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 211.

COUNT 12 – ALLEGED INFRINGEMENT BY CIPLA OF THE '643 PATENT UNDER 35 U.S.C. § 271(e)(2)

212. Plaintiffs incorporate each of the preceding paragraphs 1–207 as if fully set forth herein.

ANSWER: In response to paragraph 212, Cipla repeats and realleges its responses to the allegations of paragraphs 1–211 of the Complaint as if fully set forth herein.

213. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '643 patent was an act of infringement of the '643 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

214. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

215. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

216. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above.

ANSWER: Denied.

217. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '643 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

218. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '643 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '643 patent after approval of Cipla's ANDA.

ANSWER: Denied.

219. The foregoing actions by Cipla constitute and/or will constitute infringement of the '643 patent, active inducement of infringement of the '643 patent, and contribution to the infringement by others of the '643 patent.

ANSWER: Denied.

220. On information and belief, Cipla has acted with full knowledge of the '643 patent and without a reasonable basis for believing that it would not be liable for infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent.

ANSWER: Denied.

221. Unless Cipla is enjoined from infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 221 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 221.

COUNT 13 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '712 PATENT

222. Plaintiffs incorporate each of the preceding paragraphs 1–217 as if fully set forth herein.

ANSWER: In response to paragraph 222, Cipla repeats and realleges its responses to the allegations of paragraphs 1–221 of the Complaint as if fully set forth herein.

223. Cipla has knowledge of the '712 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 223.

224. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

225. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

226. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above.

ANSWER: Denied.

227. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '712 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

228. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '712 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '712 patent after approval of Cipla's ANDA.

ANSWER: Denied.

229. The foregoing actions by Cipla constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Denied.

230. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Denied.

231. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, and whether said claims of the '712 patent are valid.

ANSWER: Paragraph 231 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '712 patent and the validity of the '712 patent. Cipla denies the remaining allegations of paragraph 231.

232. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed

labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’712 patent and that the claims of the ’712 patent are valid.

ANSWER: Paragraph 232 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 232.

233. Cipla should be enjoined from infringing the ’712 patent, actively inducing infringement of the ’712 patent, and contributing to the infringement by others of the ’712 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 233 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 233.

COUNT 14 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE ’476 PATENT

234. Plaintiffs incorporate each of the preceding paragraphs 1–229 as if fully set forth herein.

ANSWER: In response to paragraph 234, Cipla repeats and realleges its responses to the allegations of paragraphs 1–233 of the Complaint as if fully set forth herein.

235. Cipla has knowledge of the ’476 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla’s Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 235.

236. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product would infringe at least claims 1 and/or 17 of the ’476 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

237. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

238. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 17 of the '476 patent, recited above.

ANSWER: Denied.

239. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '476 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

240. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '476 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '476 patent after approval of Cipla's ANDA.

ANSWER: Denied.

241. The foregoing actions by Cipla constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and contribution to the infringement by others of the '476 patent.

ANSWER: Denied.

242. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent.

ANSWER: Denied.

243. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 17 of the '476 patent, recited above, and whether said claims of the '476 patent are valid.

ANSWER: Paragraph 243 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '476 patent and the validity of the '476 patent. Cipla denies the remaining allegations of paragraph 243.

244. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '476 patent and that the claims of the '476 patent are valid.

ANSWER: Paragraph 244 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 244.

245. Cipla should be enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 245 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 245.

COUNT 15 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '509 PATENT

246. Plaintiffs incorporate each of the preceding paragraphs 1–241 as if fully set forth herein.

ANSWER: In response to paragraph 246, Cipla repeats and realleges its responses to the allegations of paragraphs 1–245 of the Complaint as if fully set forth herein.

247. Cipla has knowledge of the '509 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 247.

248. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

249. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

250. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '509 patent, recited above.

ANSWER: Denied.

251. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '509 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

252. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '509 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '509 patent after approval of Cipla's ANDA.

ANSWER: Denied.

253. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

ANSWER: Denied.

254. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the ’509 patent, actively inducing infringement of the ’509 patent, and contributing to the infringement by others of the ’509 patent.

ANSWER: Denied.

255. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla’s manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product with its proposed labeling according to Cipla’s ANDA will infringe at least claim 1 of the ’509 patent, recited above, and whether said claim or claims of the ’509 patent are valid.

ANSWER: Paragraph 255 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the ’509 patent and the validity of the ’509 patent. Cipla denies the remaining allegations of paragraph 255.

256. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’509 patent and that the claims of the ’509 patent are valid.

ANSWER: Paragraph 256 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 256.

257. Cipla should be enjoined from infringing the ’509 patent, actively inducing infringement of the ’509 patent, and contributing to the infringement by others of the ’509 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 257 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 257.

COUNT 16 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE ’510 PATENT

258. Plaintiffs incorporate each of the preceding paragraphs 1–253 as if fully set forth herein.

ANSWER: In response to paragraph 258, Cipla repeats and realleges its responses to the allegations of paragraphs 1–257 of the Complaint as if fully set forth herein.

259. Cipla has knowledge of the '510 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 259.

260. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

261. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

262. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

ANSWER: Denied.

263. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '510 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

264. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '510 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '510 patent after approval of Cipla's ANDA.

ANSWER: Denied.

265. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

ANSWER: Denied.

266. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

ANSWER: Denied.

267. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, and whether said claims of the '510 patent are valid.

ANSWER: Paragraph 267 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '510 patent and the validity of the '510 patent. Cipla denies the remaining allegations of paragraph 267.

268. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '510 patent and that the claims of the '510 patent are valid.

ANSWER: Paragraph 268 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 268.

269. Cipla should be enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 269 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 269.

COUNT 17 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '156 PATENT

270. Plaintiffs incorporate each of the preceding paragraphs 1–265 as if fully set forth herein.

ANSWER: In response to paragraph 270, Cipla repeats and realleges its responses to the allegations of paragraphs 1–269 of the Complaint as if fully set forth herein.

271. Cipla has knowledge of the '156 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 271.

272. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

273. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

274. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '156 patent, recited above.

ANSWER: Denied.

275. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

276. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '156 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '156 patent after approval of Cipla's ANDA.

ANSWER: Denied.

277. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

ANSWER: Denied.

278. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

ANSWER: Denied.

279. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '156 patent, recited above, and whether said claim or claims of the '156 patent are valid.

ANSWER: Paragraph 279 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '156 patent and the validity of the '156 patent. Cipla denies the remaining allegations of paragraph 279.

280. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '156 patent and that the claims of the '156 patent are valid.

ANSWER: Paragraph 280 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 280.

281. Cipla should be enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 281 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 281.

COUNT 18 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '808 PATENT

282. Plaintiffs incorporate each of the preceding paragraphs 1–277 as if fully set forth herein.

ANSWER: In response to paragraph 282, Cipla repeats and realleges its responses to the allegations of paragraphs 1–281 of the Complaint as if fully set forth herein.

283. Cipla has knowledge of the '808 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 283.

284. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

285. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

286. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '808 patent, recited above.

ANSWER: Denied.

287. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

288. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '808 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '808 patent after approval of Cipla's ANDA.

ANSWER: Denied.

289. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Denied.

290. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Denied.

291. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '808 patent, recited above, and whether said claim or claims of the '808 patent are valid.

ANSWER: Paragraph 291 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or

controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '808 patent and the validity of the '808 patent. Cipla denies the remaining allegations of paragraph 291.

292. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

ANSWER: Paragraph 292 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 292.

293. Cipla should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 293 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 293.

COUNT 19 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '512 PATENT

294. Plaintiffs incorporate each of the preceding paragraphs 1–289 as if fully set forth herein.

ANSWER: In response to paragraph 294, Cipla repeats and realleges its responses to the allegations of paragraphs 1–293 of the Complaint as if fully set forth herein.

295. Cipla has knowledge of the '512 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 295.

296. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

297. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

298. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '512 patent, recited above.

ANSWER: Denied.

299. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '512 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

300. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '512 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '512 patent after approval of Cipla's ANDA.

ANSWER: Denied.

301. The foregoing actions by Cipla constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

ANSWER: Denied.

302. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

ANSWER: Denied.

303. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '512 patent, recited above, and whether said claim or claims of the '512 patent are valid.

ANSWER: Paragraph 303 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '512 patent and the validity of the '512 patent. Cipla denies the remaining allegations of paragraph 303.

304. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '512 patent and that the claims of the '512 patent are valid.

ANSWER: Paragraph 304 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 304.

305. Cipla should be enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 305 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 305.

COUNT 20 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '447 PATENT

306. Plaintiffs incorporate each of the preceding paragraphs 1–301 as if fully set forth herein.

ANSWER: In response to paragraph 306, Cipla repeats and realleges its responses to the allegations of paragraphs 1–305 of the Complaint as if fully set forth herein.

307. Cipla has knowledge of the '447 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 307.

308. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 10 of the '447 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

309. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

310. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 10 of the '447 patent, recited above.

ANSWER: Denied.

311. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '447 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

312. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '447 patent after approval of Cipla's ANDA.

ANSWER: Denied.

313. The foregoing actions by Cipla constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and contribution to the infringement by others of the '447 patent.

ANSWER: Denied.

314. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the ’447 patent, actively inducing infringement of the ’447 patent, and contributing to the infringement by others of the ’447 patent.

ANSWER: Denied.

315. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla’s manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product with its proposed labeling according to Cipla’s ANDA will infringe at least claims 1 and/or 10 of the ’447 patent, recited above, and whether said claims of the ’447 patent are valid.

ANSWER: Paragraph 315 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the ’447 patent and the validity of the ’447 patent. Cipla denies the remaining allegations of paragraph 315.

316. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’447 patent and that the claims of the ’447 patent are valid.

ANSWER: Paragraph 316 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 316.

317. Cipla should be enjoined from infringing the ’447 patent, actively inducing infringement of the ’447 patent, and contributing to the infringement by others of the ’447 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 317 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 317.

COUNT 21 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE ’888 PATENT

318. Plaintiffs incorporate each of the preceding paragraphs 1–313 as if fully set forth herein.

ANSWER: In response to paragraph 318, Cipla repeats and realleges its responses to the allegations of paragraphs 1–317 of the Complaint as if fully set forth herein.

319. Cipla has knowledge of the '888 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 319.

320. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 25 of the '888 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

321. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

322. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 25 of the '888 patent, recited above.

ANSWER: Denied.

323. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '888 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

324. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '888 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '888 patent after approval of Cipla's ANDA.

ANSWER: Denied.

325. The foregoing actions by Cipla constitute and/or will constitute infringement of the '888 patent, active inducement of infringement of the '888 patent, and contribution to the infringement by others of the '888 patent.

ANSWER: Denied.

326. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent.

ANSWER: Denied.

327. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 25 of the '888 patent, recited above, and whether said claims of the '888 patent are valid.

ANSWER: Paragraph 327 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '888 patent and the validity of the '888 patent. Cipla denies the remaining allegations of paragraph 327.

328. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '888 patent and that the claims of the '888 patent are valid.

ANSWER: Paragraph 328 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 328.

329. Cipla should be enjoined from infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 329 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 329.

COUNT 22 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '889 PATENT

330. Plaintiffs incorporate each of the preceding paragraphs 1–325 as if fully set forth herein.

ANSWER: In response to paragraph 330, Cipla repeats and realleges its responses to the allegations of paragraphs 1–329 of the Complaint as if fully set forth herein.

331. Cipla has knowledge of the '889 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 331.

332. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '889 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

333. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

334. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 of the '889 patent, recited above.

ANSWER: Denied.

335. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '889 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

336. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '889 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '889 patent after approval of Cipla's ANDA.

ANSWER: Denied.

337. The foregoing actions by Cipla constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Denied.

338. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Denied.

339. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '889 patent, recited above, and whether said claim or claims of the '889 patent are valid.

ANSWER: Paragraph 339 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '889 patent and the validity of the '889 patent. Cipla denies the remaining allegations of paragraph 339.

340. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '889 patent and that the claims of the '889 patent are valid.

ANSWER: Paragraph 340 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 340.

341. Cipla should be enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 341 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 341.

COUNT 23 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '637 PATENT

342. Plaintiffs incorporate each of the preceding paragraphs 1–337 as if fully set forth herein.

ANSWER: In response to paragraph 342, Cipla repeats and realleges its responses to the allegations of paragraphs 1–341 of the Complaint as if fully set forth herein.

343. Cipla has knowledge of the '637 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 343.

344. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe of at least claims 1 and/or 28 of the '637 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

345. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

346. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 28 of the '637 patent, recited above.

ANSWER: Denied.

347. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '637 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

348. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '637 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '637 patent after approval of Cipla's ANDA.

ANSWER: Denied.

349. The foregoing actions by Cipla constitute and/or will constitute infringement of the '637 patent, active inducement of infringement of the '637 patent, and contribution to the infringement by others of the '637 patent.

ANSWER: Denied.

350. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent.

ANSWER: Denied.

351. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 28 of the '637 patent, recited above, and whether said claim or claims of the '637 patent are valid.

ANSWER: Paragraph 351 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or

controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '637 patent and the validity of the '637 patent. Cipla denies the remaining allegations of paragraph 351.

352. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '637 patent and that the claims of the '637 patent are valid.

ANSWER: Paragraph 352 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 352.

353. Cipla should be enjoined from infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 353 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 353.

COUNT 24 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '643 PATENT

354. Plaintiffs incorporate each of the preceding paragraphs 1–349 as if fully set forth herein.

ANSWER: In response to paragraph 354, Cipla repeats and realleges its responses to the allegations of paragraphs 1–353 of the Complaint as if fully set forth herein.

355. Cipla has knowledge of the '643 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 355.

356. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 35, 36,

37, 38, 39, and/or 40 of the '643 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

357. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

358. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above.

ANSWER: Denied.

359. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '643 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

360. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '643 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '643 patent after approval of Cipla's ANDA.

ANSWER: Denied.

361. The foregoing actions by Cipla constitute and/or will constitute infringement of the '643 patent, active inducement of infringement of the '643 patent, and contribution to the infringement by others of the '643 patent.

ANSWER: Denied.

362. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent.

ANSWER: Denied.

363. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above, and whether said claims of the '643 patent are valid.

ANSWER: Paragraph 363 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '643 patent and the validity of the '643 patent. Cipla denies the remaining allegations of paragraph 363.

364. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '643 patent and that the claims of the '643 patent are valid.

ANSWER: Paragraph 364 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 364.

365. Cipla should be enjoined from infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 365 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 365.

TEVA'S REQUEST FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required Cipla denies that Plaintiffs are entitled to any remedy or relief sought in paragraphs (a) through (j) on pages 70 through 72 of the Complaint. Should Teva receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch

Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 365 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity and Ineligibility of the '712 Patent)

Each claim of the '712 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '712 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '712 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '712 patent, either literally or under the doctrine of equivalents.

Third Defense
(Invalidity and Ineligibility of the ’476 Patent)

Each claim of the ’476 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fourth Defense
(Noninfringement of the ’476 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’476 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’476 patent, either literally or under the doctrine of equivalents.

Fifth Defense
(Invalidity and Ineligibility of the ’509 Patent)

Each claim of the ’509 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Sixth Defense
(Noninfringement of the ’509 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’509 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’509 patent, either literally or under the doctrine of equivalents.

Seventh Defense
(Invalidity and Ineligibility of the '510 Patent)

Each claim of the '510 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Eighth Defense
(Noninfringement of the '510 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '510 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '510 patent, either literally or under the doctrine of equivalents.

Ninth Defense
(Invalidity and Ineligibility of the '156 Patent)

Each claim of the '156 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Tenth Defense
(Noninfringement of the '156 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '156 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '156 patent, either literally or under the doctrine of equivalents.

Eleventh Defense
(Invalidity and Ineligibility of the '808 Patent)

Each claim of the '808 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twelfth Defense
(Noninfringement of the '808 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '808 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '808 patent, either literally or under the doctrine of equivalents.

Thirteenth Defense
(Invalidity and Ineligibility of the '512 Patent)

Each claim of the '512 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fourteenth Defense
(Noninfringement of the '512 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '512 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '512 patent, either literally or under the doctrine of equivalents.

Fifteenth Defense
(Invalidity and Ineligibility of the '447 Patent)

Each claim of the '447 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Sixteenth Defense
(Noninfringement of the '447 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '447 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent, either literally or under the doctrine of equivalents.

Seventeenth Defense
(Invalidity and Ineligibility of the '888 Patent)

Each claim of the '888 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Eighteenth Defense
(Noninfringement of the '888 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '888 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '888 patent, either literally or under the doctrine of equivalents.

Nineteenth Defense
(Invalidity and Ineligibility of the '889 Patent)

Each claim of the '889 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twentieth Defense
(Noninfringement of the '889 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '889 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '889 patent, either literally or under the doctrine of equivalents.

Twenty-First Defense
(Invalidity and Ineligibility of the '637 Patent)

Each claim of the '637 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twenty-Second Defense
(Noninfringement of the '637 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '637 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '637 patent, either literally or under the doctrine of equivalents.

Twenty-Third Defense
(Invalidity and Ineligibility of the '643 Patent)

Each claim of the '643 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twenty-Fourth Defense
(Noninfringement of the '643 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '643 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '643 patent, either literally or under the doctrine of equivalents.

Twenty-Fifth Defense
(Waiver)

Plaintiffs have waived any defect in the manner in which Cipla served Cipla's Notice Letter and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letter.

Twenty-Sixth Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, equitable estoppel, unclean hands, waiver, implied waiver, acquiescence, disclaimer, judicial estoppel, and/or other equitable doctrines.

Twenty-Seventh Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Twenty-Eighth Defense
(No Exceptional Case)

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Twenty-Ninth Defense
(No Willful Infringement)

Cipla has not willfully infringed any claim of the Patents-in-Suit.

Thirtieth Defense
(Ensnarement)

To the extent Plaintiffs claims infringement of one or more claims of the patent-in-suit under the doctrine of equivalents, Plaintiffs' claims are barred under the ensnarement doctrine, which prohibits Plaintiffs from asserting an infringement theory under the doctrine of equivalents that encompasses or ensnares the prior art.

Thirty-First Defense
(Lack of Standing)

To the extent that Plaintiffs did not, or do not, hold all substantial rights, title, and interest to the Patents-in-Suit, Plaintiffs lack standing to bring, or maintain, this lawsuit in connection with such patent.

Thirty-Second Defense
(Reservation of Defenses)

Defendants reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future, including, but not limited to, those related to the unenforceability of any claim of the Patents-in-Suit based on inequitable conduct, as may be determined through discovery and further factual investigation in this actions.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs Teva Branded Pharmaceutical Products, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs" or "Counterclaim Defendants"), other than those expressly admitted herein, Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") (collectively, the "Patents-in-Suit") are invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application ("ANDA") No. 219000 ("Cipla's ANDA Product"):

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") is a company

organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, upon information and belief and based on the allegations in the Complaint, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Norton (Waterford) Ltd. ("Norton") is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

6. Upon information and belief, and based on the FDA's Orange Book, Counterclaim Defendant Norton is the holder of New Drug Application ("NDA") No. 207921. Based on the allegations in the complaint, Counterclaim Defendant Teva is the holder of New Drug Application ("NDA") No. 207921.

7. Upon information and belief, Counterclaim Defendants currently promote and market Qvar RediHaler® in the United States.

Jurisdiction and Venue

8. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

9. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

10. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

11. On or about February 16, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the Patents-in-Suit. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the Patents-in-Suit and the invalidity of the Patents-in-Suit.

The Patents-in-Suit

12. Based on the allegations in the Complaint, the '712 patent, entitled "Metered-Dose Inhaler," was issued on March 13, 2012. The face of the '712 patent lists Ivax Pharmaceuticals Ireland as the assignee. According to the U.S. Patent and Trademark Office assignment database, Ivax Pharmaceuticals Ireland is listed as the assignee of the '712 patent.

13. Based on the allegations in the Complaint, the '476 patent, entitled "Inhaler," was issued on January 13, 2015. The face of the '476 patent lists Ivax Pharmaceuticals Ireland as the assignee. According to the U.S. Patent and Trademark Office assignment database, Ivax Pharmaceuticals Ireland is listed as the assignee of the '476 patent.

14. Based on the allegations in the Complaint, the '509 patent, entitled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement," was issued on July 17, 2018. The face of the

'509 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as assignees.

15. Based on the allegations in the Complaint, the '510 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof," was issued on July 17, 2018. The face of the '510 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as assignees.

16. Based on the allegations in the Complaint, the '156 patent, entitled "Dose Counter for Inhaler and Method for Counting Doses," was issued on October 2, 2018. The face of the '156 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as assignees.

17. Based on the allegations in the Complaint, the '808 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," was issued on February 18, 2020. The face of the '808 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as assignees.

18. Based on the allegations in the Complaint, the '512 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," was issued on June 30, 2020. The face of the '512 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as assignees.

19. Based on the allegations in the Complaint, the '447 patent, entitled "Breath Actuated Inhaler," was issued on October 6, 2020. The face of the '447 patent lists Norton (Waterford) Limited as the assignee. Norton (Waterford) Limited is also listed as the assignee of the '447 patent in the U.S. Patent and Trademark Office assignment database.

20. Based on the allegations in the Complaint, the '888 patent, entitled "Inhalers and Related Methods," was issued on July 26, 2022. The face of the '888 patent lists Norton (Waterford) Limited as the assignee. Norton (Waterford) Limited is also listed as the assignee of the '888 patent in the U.S. Patent and Trademark Office assignment database.

21. Based on the allegations in the Complaint, the '889 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," was issued on July 26, 2022. The face of the '889 patent lists Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland as the assignees.

22. Based on the allegations in the Complaint, the '637 patent, entitled "Inhalers and Related Methods," was issued on January 24, 2023. The face of the '637 patent lists Norton (Waterford) Limited as the assignee. Norton (Waterford) Limited is listed as the assignee of the '637 patent in the U.S. Patent and Trademark Office assignment database.

23. Based on the allegations in the Complaint, the '643 patent, entitled "Inhalers and Related Methods," was issued on February 21, 2023. The face of the '643 patent lists Norton (Waterford) Limited as the assignee. Norton (Waterford) Limited is also listed as the assignee of the '643 patent in the U.S. Patent and Trademark Office assignment database.

24. The Patents-in-Suit are listed in the electronic version of the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in association with QVAR REDIHALER®.

25. On January 4, 2024, pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 319.95, Cipla sent Plaintiffs notification of Paragraph IV Certification for the Patents-in-Suit with respect to Cipla's Abbreviated New Drug Application ("ANDA") No. 219000 ("Cipla's ANDA"), which

seeks approval from the FDA to engage in the commercial manufacture, distribution, use, offer for sale, sale, and/or import of the product described in Cipla's ANDA ("Cipla's ANDA Product") ("Cipla's First Notice Letter").

26. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla's First Notice Letter included, among other things, Cipla's detailed factual and legal basis for the paragraph IV certification regarding the Patents-in-Suit as it pertains to Cipla's ANDA Product and an offer of confidential access ("Cipla's First OCA").

27. On or about February 16, 2024, Counterclaim Defendants brought this present action alleging infringement of the Patents-in-Suit.

First Counterclaim
(Declaratory Judgment of Noninfringement of the '712 Patent)

28. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 27 of the Counterclaims as if fully set forth herein.

29. Counterclaim Defendants have accused Cipla of infringing the '712 patent.

30. Cipla denies infringement of the '712 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '712 patent.

31. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '712 patent.

32. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '712 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the '712 Patent)

33. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 32 of the Counterclaims as if fully set forth herein.

34. The claims of the '712 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

35. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '712 patent are not infringed by Cipla's ANDA Product and/or are invalid.

36. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '712 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

37. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '712 patent.

38. Cipla is entitled to a judicial declaration that all claims of the '712 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code

including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Third Counterclaim
(Declaratory Judgment of Noninfringement of the '476 Patent)

39. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 38 of the Counterclaims as if fully set forth herein.

40. Counterclaim Defendants have accused Cipla of infringing the '476 patent.

41. Cipla denies infringement of the '476 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '476 patent.

42. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '476 patent.

43. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '476 patent.

Fourth Counterclaim
(Declaratory Judgment of Invalidity of the '476 Patent)

44. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 43 of the Counterclaims as if fully set forth herein.

45. The claims of the '476 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

46. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '476 patent are not infringed by Cipla's ANDA Product and/or are invalid.

47. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '476 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

48. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '476 patent.

49. Cipla is entitled to a judicial declaration that all claims of the '476 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fifth Counterclaim
(Declaratory Judgment of Noninfringement of the '509 Patent)

50. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 49 of the Counterclaims as if fully set forth herein.

51. Counterclaim Defendants have accused Cipla of infringing the '509 patent.

52. Cipla denies infringement of the '509 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '509 patent.

53. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '509 patent.

54. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '509 patent.

Sixth Counterclaim
(Declaratory Judgment of Invalidity of the '509 Patent)

55. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 54 of the Counterclaims as if fully set forth herein.

56. The claims of the '509 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

57. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '509 patent are not infringed by Cipla's ANDA Product and/or are invalid.

58. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '509 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

59. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '509 patent.

60. Cipla is entitled to a judicial declaration that all claims of the '509 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Seventh Counterclaim
(Declaratory Judgment of Noninfringement of the '510 Patent)

61. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 60 of the Counterclaims as if fully set forth herein.

62. Counterclaim Defendants have accused Cipla of infringing the '510 patent.

63. Cipla denies infringement of the '510 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '510 patent.

64. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '510 patent.

65. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '510 patent.

Eighth Counterclaim
(Declaratory Judgment of Invalidity of the '510 Patent)

66. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 65 of the Counterclaims as if fully set forth herein.

67. The claims of the '510 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

68. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '510 patent are not infringed by Cipla's ANDA Product and/or are invalid.

69. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '510 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

70. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '510 patent.

71. Cipla is entitled to a judicial declaration that all claims of the '510 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Ninth Counterclaim
(Declaratory Judgment of Noninfringement of the '156 Patent)

72. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 71 of the Counterclaims as if fully set forth herein.

73. Counterclaim Defendants have accused Cipla of infringing the '156 patent.

74. Cipla denies infringement of the '156 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '156 patent.

75. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '156 patent.

76. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '156 patent.

Tenth Counterclaim
(Declaratory Judgment of Invalidity of the '156 Patent)

77. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 76 of the Counterclaims as if fully set forth herein.

78. The claims of the '156 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

79. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '156 patent are not infringed by Cipla's ANDA Product and/or are invalid.

80. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '156 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

81. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '156 patent.

82. Cipla is entitled to a judicial declaration that all claims of the '156 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Eleventh Counterclaim
(Declaratory Judgment of Noninfringement of the '808 Patent)

83. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 82 of the Counterclaims as if fully set forth herein.

84. Counterclaim Defendants have accused Cipla of infringing the '808 patent.

85. Cipla denies infringement of the '808 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '808 patent.

86. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '808 patent.

87. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '808 patent.

Twelfth Counterclaim
(Declaratory Judgment of Invalidity of the '808 Patent)

88. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 87 of the Counterclaims as if fully set forth herein.

89. The claims of the '808 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

90. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '808 patent are not infringed by Cipla's ANDA Product and/or are invalid.

91. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '808 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

92. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '808 patent.

93. Cipla is entitled to a judicial declaration that all claims of the '808 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Thirteenth Counterclaim
(Declaratory Judgment of Noninfringement of the '512 Patent)

94. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 93 of the Counterclaims as if fully set forth herein.

95. Counterclaim Defendants have accused Cipla of infringing the '512 patent.

96. Cipla denies infringement of the ’512 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the ’512 patent.

97. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’512 patent.

98. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’512 patent.

Fourteenth Counterclaim
(Declaratory Judgment of Invalidity of the ’512 Patent)

99. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 98 of the Counterclaims as if fully set forth herein.

100. The claims of the ’512 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

101. For at least the reasons stated in Cipla’s Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’512 patent are not infringed by Cipla’s ANDA Product and/or are invalid.

102. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '512 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

103. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '512 patent.

104. Cipla is entitled to a judicial declaration that all claims of the '512 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fifteenth Counterclaim
(Declaratory Judgment of Noninfringement of the '447 Patent)

105. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 104 of the Counterclaims as if fully set forth herein.

106. Counterclaim Defendants have accused Cipla of infringing the '447 patent.

107. Cipla denies infringement of the '447 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '447 patent.

108. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '447 patent.

109. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '447 patent.

Sixteenth Counterclaim
(Declaratory Judgment of Invalidity of the '447 Patent)

110. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 109 of the Counterclaims as if fully set forth herein.

111. The claims of the '447 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

112. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '447 patent are not infringed by Cipla's ANDA Product and/or are invalid.

113. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '447 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

114. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '447 patent.

115. Cipla is entitled to a judicial declaration that all claims of the '447 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Seventeenth Counterclaim
(Declaratory Judgment for Noninfringement of the '888 Patent)

116. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 115 of the Counterclaims as if fully set forth herein.

117. Counterclaim Defendants have accused Cipla of infringing the '888 patent.

118. Cipla denies infringement of the '888 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '888 patent.

119. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '888 patent.

120. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '888 patent.

Eighteenth Counterclaim
(Declaratory Judgment of Invalidity of the '888 Patent)

121. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 120 of the Counterclaims as if fully set forth herein.

122. The claims of the '888 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

123. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '888 patent are not infringed by Cipla's ANDA Product and/or are invalid.

124. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '888 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

125. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '888 patent.

126. Cipla is entitled to a judicial declaration that all claims of the '888 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Nineteenth Counterclaim
(Declaratory Judgment of Noninfringement of the '889 Patent)

127. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 126 of the Counterclaims as if fully set forth herein.

128. Counterclaim Defendants have accused Cipla of infringing the '889 patent.

129. Cipla denies infringement of the '889 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '889 patent.

130. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '889 patent.

131. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable and enforceable claim of the '889 patent.

Twentieth Counterclaim
(Declaratory Judgment of Invalidity of the '889 Patent)

132. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 131 of the Counterclaims as if fully set forth herein.

133. The claims of the '889 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

134. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '889 patent are not infringed by Cipla's ANDA Product and/or are invalid.

135. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '889 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

136. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '889 patent.

137. Cipla is entitled to a judicial declaration that all claims of the '889 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twenty-First Counterclaim
(Declaratory Judgment for Noninfringement of the '637 Patent)

138. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 137 of the Counterclaims as if fully set forth herein.

139. Counterclaim Defendants have accused Cipla of infringing the '637 patent.

140. Cipla denies infringement of the ’637 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the ’637 patent.

141. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’637 patent.

142. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’637 patent.

Twenty-Second Counterclaim
(Declaratory Judgment of Invalidity of the ’637 Patent)

143. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 142 of the Counterclaims as if fully set forth herein.

144. The claims of the ’637 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

145. For at least the reasons stated in Cipla’s Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’637 patent are not infringed by Cipla’s ANDA Product and/or are invalid.

146. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '637 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

147. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '637 patent.

148. Cipla is entitled to a judicial declaration that all claims of the '637 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Twenty-Third Counterclaim
(Declaratory Judgment of Non-infringement of the '643 Patent)

149. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 148 of the Counterclaims as if fully set forth herein.

150. Counterclaim Defendants have accused Cipla of infringing the '643 patent.

151. Cipla denies infringement of the '643 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '643 patent.

152. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '643 patent.

153. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '643 patent.

Twenty-Fourth Counterclaim
(Declaratory Judgment of Invalidity of the '643 Patent)

154. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 153 of the Counterclaims as if fully set forth herein.

155. The claims of the '643 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

156. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '643 patent are not infringed by Cipla's ANDA Product and/or are invalid.

157. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '643 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

158. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '643 patent.

159. Cipla is entitled to a judicial declaration that all claims of the '643 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not and will not directly or indirectly infringe any claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patents-in-Suit are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the Patents-in-Suit against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

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Attorneys for Defendants/Counterclaim-Plaintiffs
Cipla Limited and Cipla USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that, to the best of my knowledge, the following actions involve some of the same patents as the Patents-in-Suit:

- *Teva Branded Pharmaceutical Products R&D, Inc.*, et al., *v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856-SRC-MAH, pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted, *inter alia*, patents related to the Patents-in-Suit against Defendants in connection with Defendants' submission of ANDA No. 219000;
- *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-07162-SRC-MAH, in which Plaintiffs asserted, *inter alia*, patents related to the Patents-in-Suit against Defendants in connection with Defendants' submission of ANDA No. 21900;
- *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Deva Holding A.S.*, No. 2:24-cv-04404-SRC-MAH, pending before the United States District Court for the District of New Jersey, involves U.S. Patent Nos. 8,132,712, 10,022,509, 10,022,510, 10,086,156, 10,561,808, 10,695,512, and 11,395,889;
- *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Amneal Pharmaceuticals of New York, LLC, et al.*, No. 2:23-cv-20964-JXN-MAH, pending before the United States District Court for the District of New Jersey, involves U.S. Patent Nos. 8,132,712, 10,561,808, 10,695,512, and 11,395,889;

- *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Cipla Ltd. et al.*, No. 2:20-cv-10172-JXN-MAH, proceeded to final judgment in the United States District Court for the District of New Jersey, involved U.S. Patent Nos. 10,022,509, 10,022,510, 10,086,156, and 10,561,808;
- *Cipla Ltd. et al. v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, No. 2023-2241, pending before the Federal Circuit Court of Appeals, involves U.S. Patent No. 10,561,808.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action seeks declaratory judgement and therefore this action is not appropriate for compulsory arbitration.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

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Attorneys for Defendants/Counterclaim-Plaintiffs
Cipla USA, Inc. and Cipla Limited

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. 2:24-cv-00909 Hon. Stanley R. Chesler, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **CERTIFICATE OF SERVICE** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate Defenses, and Counterclaims, Fed. R. Civ. P. 7.1 Corporate Disclosure Statement, and this certificate of service to be served upon all counsel of record by CM/ECF and e-mail.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

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